REMARKS

Applicants would like to thank Examiner Sharareh for taking the time to discuss the pending rejections with David Abraham, Sylvia Seroff, and the undersigned during a telephonic interview on April 13, 2004. During the telephonic interview, the Examiner expressed the view that the patentable aspects of claims were allegedly taught by the general combination of the Hoover, Jacobs, Wong and Misra patents. However, the combination of these references fails to teach or suggest using color detection to determine the orientation of tablets or tablets in which their orientation is detectable by color detection. The Examiner also expressed the view that the method claims (claims 18-21) allegedly lacked a positive recitation of "placing a spot location" and "detecting a spot location." Applicants direct the Examiner's attention to the language of the method claims "detecting the color at a spot location on a side of the tablet corresponding to one or another differently-colored formulation layer depending on the formulation orientation of the tablet." Applicants consider this a positive recitation of a spot location. Applicants have also positively recited this detecting step within the method claims. Applicants respect reconsideration of the rejections, the specifics of which are addressed below, in light of the discussion had on April 13, 2004.

Claims 1-31 are pending with claims 1-17 withdrawn from consideration. Claims 18-31 stand rejected. Claims 22 and 27 have been amended to correct a grammatical error and to more clearly define the claimed tablets' detectability. Support for these amendments may be found throughout the specification, for example, on page 7, line 29 – page 8, line 8.

Claims 22-31 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 5,464,631 to Hoover, *et al.* ("the Hoover patent") and U.S. Patent No. 5,824,338 to Jacobs, *et al.* ("the Jacobs patent") in view of U.S. Patent No. 5,785,994 to Wong, *et al.* ("the Wong patent"). Applicants traverse this rejection.

The basis for the instant rejection appears to be that the Hoover patent discloses the subject matter of claims 22-24 and 27-29. The Office Action at page 4, for example, asserts that "Hoovers' [sic] teachings meet the limitations of claims 22-24, 27-29."

The Hoover patent, however, clearly does not disclose the subject matter of these claims. Specifically, disclosure is lacking at least with respect to the recitation of first,

second and third layers that "are compressed into a capsule-shaped osmotic tablet" (Claim 22, lines 5-6; Claim 27, line 8). The Office Action, for example, asserts that the Hoover patent discloses compressing two layers of material and then merely *encasing* the resulting tablet in a gelatin capsule (Office Action at page 3). Therefore, Hoover's dosage forms have, at most, two compressed layers whereas the claimed tablets have three. As such, there is no basis for the Office Action's assertion that the Hoover patent's teachings "meet the limitation of claims 22-24, 27-29."

Significantly, the Office Action fails to identify any prior art that would remedy this deficiency. The Office Action, for example, does not rely upon the Jacobs patent for any alleged teaching relating to layer compression but, rather, for its teaching that gelatin coatings can be clear or colored (Office Action at page 4). Similarly, although the Office Action asserts that the Wong patent discloses a tablet formed by compressing three layers to form a solid core (Office Action at page 5), the Office Action does not explain how or why those of ordinary skill would have combined this disclosure with the Hoover patent's teachings, much less how or why they would have combined it in a way that would have produced a claimed invention. Moreover, the Wong patent discloses a drug free first layer, one drug layer, and a push layer. (see column 20, lines 30-31), whereas claims 22 and 27 of the present application recite that both the first and second layers comprise a drug ingredient. Therefore, contrary to the Office Action's assertions on page 5, modifying the sustained dosage forms disclosed in the Wong patent to incorporate the Hoover patent's teaching relating to partially-covering tablets with hard-gelatin or the Jacobs patent's teaching relating to coloring gelatin would not have produced any invention recited in claims 22-31. The resulting product would also lack the claimed disposition of colorants. Accordingly, the rejection of claims 22-31 for alleged obviousness is improper and should be withdrawn. *In re Payne*, 203 U.S.P.Q. 245, 255 (C.C.P.A. 1979) (references relied upon to support rejection under §103 must place the claimed invention in the possession of the public).

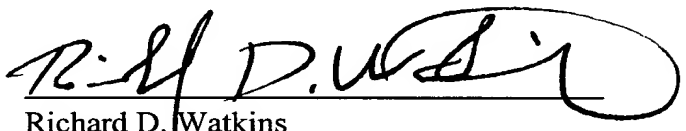
Claims 18-31 have been rejected as allegedly being unpatentable over the Hoover, Jacobs, and Wong patents in view of the disclosure in U.S. Patent No. 5,422,831 to Misra, *et al.* ("the Misra patent") allegedly demonstrating that use of a detector to determine color characteristics of dosage forms would have been conventional (Office Action at page 6). However, the Misra method is different from the claimed methods (*i.e.*, those recited in

claims 18-21), in which a color detector is directed to a spot on the side a tablet to detect the formulation orientation of the tablet. The Office Action has not shown any disclosure in the Misra patent of orientation detection based on color.

Even if one skilled in the art combined the teachings of the Misra patent with the other cited references, none of its alleged teachings related to defect detection would have remedied the structural deficiencies left by the combination of the Hoover, Jacobs, and Wong patents. For example, there has been no showing of a tablet formulation wherein the formulation orientation of the tablet is detectable by a color detector directed at the spot location on the side of the tablet. The rejection for alleged obviousness is improper and should be withdrawn.

Applicants believe that the foregoing constitutes a complete and full response to the Office Action of record. Applicants respectfully submit that this application is now in condition for allowance. Accordingly, an indication of allowability and an early Notice of Allowance are respectfully requested.

Date: April 14, 2004



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